

**REMARKS**

This paper is responsive to the Office Action mailed July 13, 2004. Claims 1-63 were pending in the application, claims 1, 2, 20-33, 42, and 44 were under consideration, and claims 3-19, 34-41, 43, and 45-63 were withdrawn by the PTO as directed to a non-elected invention.

In this paper, claims 1, 24, 25, 42, and 44 are amended, claims 34-41 are cancelled without prejudice to Applicants' right to pursue the subject matter of the cancelled claims in one or more related continuation, divisional, or continuation-in-part applications, and restriction between groups I, II, and III is traversed. Thus, following entry of the present amendment, claims 1-33 and 42-63 remain pending, claims 1, 2, 20-33, 42, and 44 are under consideration, claims 34-41 are cancelled without prejudice, claims 45-63 stand withdrawn, and claims 3-19 and 43 are earnestly requested to be reinstated and examined on the merits.

Applicants kindly thank the PTO for indicating that the examined claims are free from the art of record.

**I. The Amendments to the Claims**

In the present amendment, claims 1, 24, 25, 42, and 44 are amended, and claims 34-41 are cancelled without prejudice. The amendments to claims 1, 24, 25, 42, and 44 are fully supported by the application as filed. Accordingly, the amendments to claims 1, 24, 25, 42, and 44 do not present new matter.

In particular, support for the amendment to claim 1 may be found, for example, in claim 1 as originally filed, in Figures 1, 2 and 3, and in the specification at paragraphs 48, 55, 76, 77, 101, and 102. Support for the amendment to claim 24 may be found, for example, in claim 24 as originally filed. Support for the amendment to claim 25 may be found, for example, in claim 25 as originally filed, in Figure 1, and in the specification at paragraphs 55, 76, 77, 101 and 102. Support for the amendment to claim 42 may be found, for example, in claim 42 as originally filed. Support for the amendment to claim 44 may be found, for example, in claim 44 as filed and in the specification at paragraphs 145 and 146.

More specifically, the exemplary compounds presented in the Figures 1, 2, and 3, and the definitions and preferred embodiments from the above-identified paragraphs of the specification describe to one of skill in the art how the X and Y moieties previously recited by claims 1 and 25 are integrated into the ring structure of the core and how they can form the compounds recited by claim 26. Similarly, this support also shows the skilled artisan the R<sub>1</sub> and R<sub>2</sub> moieties previously recited by claim 1 connect with the remainder of the molecule.

Thus, the clarifying amendments to claims 1 and 25 do not change but merely remove any possible doubt as to the manner in which X, Y, R<sub>1</sub> and R<sub>2</sub> form and/or connect with the remainder of the molecule. Accordingly, the amendments to claims 1 and 25 are fully supported by the application as filed.

Applicants respectfully submit that since the specification and claims as originally filed fully support the amendments to claims 1, 24, 25, 42, and 44, the amendments present no new matter. Accordingly, entry of the instant amendment under 37 C.F.R. § 1.111 is respectfully requested.

## **II. Restriction**

The PTO has restricted the claims of the present application into seven restriction groups. Each of Groups I, II, and III relate to compounds that fall within the genus defined by formula I; group IV relates to compounds of formulae III, VI, IX, and XII; and groups V, VI, and VII relate to methods of using and/or identifying a compound of the invention. The PTO contends that the inventions of Groups I, II, and III are unrelated because the inventions of these groups allegedly have a different core and hence different bondings and properties. Further, the PTO asserts that a preliminary search on the core gave numerous iterations, which allegedly indicates that the core of the compounds of Groups I, II, and III is not Applicants' contribution to the art.

First, Applicants respectfully request that the PTO try to completely search the genus of compounds defined by claim 1 as amended. Perhaps part of the difficulty experienced by the PTO in searching this genus is the omission of the L and B moieties of formula I from the core that was searched. In addition, Applicants do not agree with the PTO's assertion that the number of iterations required for a search is somehow reflective of the state of the art and that the number of iterations of the search is in any way probative of the novelty and/or non-obviousness of the claimed genus.

In any event, Applicants disagree with the PTO's contention that the compounds of Groups I, II, and III have a different core and therefore different bonding and properties. In fact, the compounds defined by each of Groups I, II, and III all have the core defined by the genus of formula I as recited by claim 1. Thus, claim 1 defines a class of compounds that is generic to each of the individual species included in Groups I, II, and III. As such, claim 1 constitutes a generic linking claim, which links the distinct species that are present in Groups I, II, and III. Further, claim 1 defines this genus using Markush groups, and is thus a Markush-type claim. *See* M.P.E.P. § 803.02.

Applicants believe that the proper treatment for examination of a generic Markush-type claim that cannot be examined without a burdensome search is to require a provisional election of species to facilitate examination. *See* M.P.E.P. § 803.02; *see also* M.P.E.P. §§ 808.01 and 809. Upon determining that the elected species is free of art, the search will be extended to the non-elected species to the extent necessary to determine the patentability of the generic claim. *See* M.P.E.P. § 803.02. Assuming that no art anticipates or renders obvious the generic claim, Applicants are entitled to issuance of the generic claim and claims directed to a reasonable number of species readable thereon. *See* M.P.E.P. §§ 803.02, 808.01, and 809.

Finally, Applicants note that the claims defining the methods of groups V, VI, and VII each ultimately depend from claim 1. The PTO's attention is respectfully invited to M.P.E.P. § 821.04, which indicates that withdrawn process claims that depend from or otherwise include all limitations of an allowable product claim will be rejoined. *See* M.P.E.P. § 821.04. As such, upon allowance of claim 1, Applicants are entitled as of right to rejoinder of the claims of groups V, VI, and VII and allowance of such claims assuming they satisfy all other requirements of patentability.

### **III. The Indefiniteness Rejection Should Be Withdrawn**

Claims 1, 2, 20-25, 27-33, 42, and 44 stand rejected as allegedly indefinite under 35 U.S.C. § 112, second paragraph. In particular, the PTO contends that the claims do not adequately specify how the X, Y, R<sub>1</sub>, and R<sub>2</sub> moieties would attach to the core ring structure to form the compounds recited by claim 26. In addition, the PTO asserts that one of the compounds of claim 26 recites a compound that comprises a hydroxyl moiety attached to a five or six membered spiro ring, which hydroxyl moiety lacks sufficient antecedent basis.

As an initial matter, Applicants note that claims 1, 2, 20-25, 27-33, 42, and 44 stand rejected as allegedly indefinite, but that the PTO has not identified an alleged indefiniteness issue with any claim beyond claims 1 and 26. Applicants believe that the remaining claims stand rejected for depending from a rejected claim, and respond accordingly. If this belief is incorrect, Applicants earnestly request that the PTO correct this misapprehension for the record.

As discussed above, the present paper presents an amendment to claims 1 and 25 that clarifies the connectivity the X, Y, R<sub>1</sub>, and R<sub>2</sub> moieties. Applicants believe that the skilled artisan could recognize the connectivity of these moieties from claims 1 and 25 as previously pending, as discussed above, and believe that the clarifying amendments remove any possible

ambiguity. Thus, Applicants respectfully submit that amended claims 1 and 25 are not indefinite and that the rejection is moot in view of the amendments to such claims.

Moreover, Applicants respectfully submit that the compounds with a hydroxyl moiety attached to the five or six membered spiro ring structure recited by claim 26 find antecedent support in claim 1, both as previously pending and as amended. In particular, such compounds find antecedent support in groups X and Y recited by claim 1. For example, a five membered spiro ring substituted with a hydroxyl group can be formed when X is unsubstituted C<sub>1</sub> alkylene and Y is C<sub>1</sub> alkylene substituted with OR<sup>3</sup>, wherein R<sup>3</sup> is hydrogen. Similarly, an exemplary six membered spiro ring substituted with a hydroxyl group can be formed when X is unsubstituted C<sub>2</sub> alkylene and Y is C<sub>1</sub> alkylene substituted with OR<sup>3</sup>, wherein R<sup>3</sup> is hydrogen. Other exemplary moieties recited for X or Y can also be used to provide antecedent basis for such structures. Therefore, the compounds with a hydroxyl moiety attached to the five or six membered spiro ring structure recited by claim 26 find antecedent support in claim 1. Accordingly, claim 26 is not indefinite.

In view of the foregoing, Applicants respectfully submit that the rejection of claims 1, 2, 20-25, 27-33, 42, and 44 is either erroneous or moot. Therefore, Applicants respectfully request that the rejection of claims 1, 2, 20-25, 27-33, 42, and 44 as indefinite under 35 U.S.C. § 112, second paragraph, be withdrawn.

#### **IV. The Enablement Rejection Should Be Withdrawn**

Claim 44 stands rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not enable treatment of all of the disorders recited by the claim. Without acquiescing to the propriety of the rejection, and solely to expedite prosecution of the claims, claim 44 has been amended to recite a method for treating metabolic disorders. Accordingly, Applicants respectfully submit that the rejection of claim 44 for lack of enablement is moot. Therefore, Applicants respectfully request withdrawal of the rejection of claim 44 as not enabled under 35 U.S.C. § 112, first paragraph.

Nonetheless, Applicants emphasize for the record that the rejection of claim 44 as not enabled by the specification is not supported by either law or fact. The PTO bears the initial burden of setting forth a *prima facie* case of non-enablement that presents “a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention in the specification of the application...” *In re Wright*, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993). Further, the PTO’s *prima facie* case should address each of the *Wands* factors since “[i]t is improper to conclude

that a disclosure is not enabling based on an analysis of only one of the [*Wands*] factors while ignoring one or more of the others.” See MPEP § 2164.01(a), citing *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1407 (Fed Cir 1988). Applicants note that the PTO has completely failed to discuss any of the *Wands* factors beyond the predictability of the art, in contravention of the PTO’s own rule.

Further, the PTO has presented no evidence of non-enablement and no reason to doubt Applicants’ statements that the compounds of the invention are useful to treat the diseases previously recited by claim 44. In fact, the PTO makes a bare assertion that drugs do not have an umbrella efficacy of treating the diseases listed in claim 44 that is completely unsupported by any evidence of record.

**V. The Written Description Rejection Should Be Withdrawn**

Claim 1 stands rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not describe prodrugs of the compounds of the invention sufficiently to demonstrate Applicants’ possession of the claimed invention at the time the application was filed. Without acquiescing to the propriety of the rejection, and solely to expedite prosecution of the claims, claim 1 has been amended to delete the recitation of “prodrug.” Accordingly, Applicants respectfully submit that the rejection of claim 1 for lack of written description is moot. Therefore, Applicants respectfully request withdrawal of the rejection of claim 1 as not described under 35 U.S.C. § 112, first paragraph.

**CONCLUSION**

In light of the above amendments and remarks, Applicants respectfully request that the PTO reinstate withdrawn claims 3-19 and 43 and reconsider this application with a view towards allowance. The PTO is invited to call the undersigned attorney at (650) 739-3983 if a telephone call could help resolve any remaining items.

Respectfully submitted,

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